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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/065,672	04/23/1998	PATRICIA A. BILLING-MEDEL	6086.US.P1	7811

23492 7590 07/30/2003

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EXAMINER	
TURNER, SHARON L	
ART UNIT	**PAPER NUMBER**
1647	28

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/065,672	BILLING-MEDEL ET AL.	
	Examiner	Art Unit	
	Sharon L. Turner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-59,62,63 and 66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-59,62,63 and 66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 April 1998* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Amendment

1. The amendment filed 5-19-03 has been entered into the record and has been fully considered. Claims 54-56, 60-61, 64-65 and 67-68 are canceled. Claims 57-59, 62-63 and 66 are pending.

2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

3. As a result of Applicant's amendment, all rejections not reiterated herein have been withdrawn by the Examiner.

Rejections Maintained

Election/Restrictions

4. Applicant's election of Group I, claims 57-59, 62-63 and 66 to the extent of SEQ ID NO:5, residues 1-276 in Paper No. 24 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Priority

5. Applicant's claim to priority under 35 USC 120 to patent application 08/838,968 filed 4-23-1997 is acknowledged. However, instant claims 57-59, 62-63 and 66 do not obtain the benefit of the priority date as the '968 application does not provide support for 100% identity of SEQ ID Nos:5, residues 1-276 as instantly claimed, see also Figure 1. The priority document is thus non-enabling with respect to 35 USC 112 for instantly claimed invention. Therefore the effective filing date of instant claims 57-59, 62-63 and 66 is the instant filing dated of 4-23-98.

Applicant's again argue in the response of 5-19-03 that priority is provided in that SEQ ID NO:4 residues 1-276 of the priority document are the same as instant SEQ ID NO:5 residues 1-276.

Applicant's arguments filed 5-19-03 have been fully considered but are not persuasive. As previously noted and as set forth in the new matter rejection of record, the specification does not provide support for the recitation with respect to SEQ ID NO:5, residues 1-276. While the sequences may be the same there is no support in the specification for the probe of residues 1-276 of SEQ ID NO:5.

Specification

6. The disclosure is objected to because of the following informalities: The specification throughout references sequence identifiers as "SEQUENCE ID NO X". However, MPEP 2422 (d) designates that the required reference be "SEQ ID NO:X".

Appropriate correction is required.

Applicants argue in the response of 5-19-03 that the specification as amended complies and the objection should be withdrawn.

Applicant's arguments filed 5-19-03 have been fully considered but are not persuasive. The specification was not amended to "SEQ ID NO:" as in MPEP 2422(d) but to "SEQUENCE ID NO:".

Claim Rejections - 35 USC § 101 and 112

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 57-59, 62-63 and 66 are rejected under 35 U.S.C. 101, because the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility.

The specification contemplates the use of the disclosed nucleic acids for the identification of markers as indicative of a prostate tissue disease or condition, see in particular p. 11, lines 16-17. The specification further discloses that the isolated nucleic acids of the invention are specific to a PS128 polynucleotide and that the nucleic acids may be used to detect the PS128 sequence in a test sample, see in particular p. 4, lines 10-11. Yet the specification discloses that PS128 is expressed in tissues other than prostate and in normal prostate as well as in prostate cancer tissue, see in particular Figures 3-4. In addition, the claims recite homologous sequences which may not specifically detect the designated PS128 sequence, but alternatively would detect related sequences. Thus the designated utility does not appear to be either specific and substantial because the sequences detect sequences from tissues other than prostate cancer and for prostate regardless of disease or condition. Thus, the use for the nucleic acids appears to merely rely on the inherent properties of any nucleic acid to hybridize to complementary sequences. Therefore, the disclosed nucleic acids merely constitute research reagents for further experimentation to discover the "real-world" use or

significance of expression. The examiner further notes that the specification fails to disclose a PS128 gene, open reading frame, polypeptide or epitope for which the nucleic acid fragments are specific. For these reasons there does not appear to be either a specific and substantial, asserted utility or a well-established utility for the claimed nucleic acids.

Applicant's previously filed arguments (6-5-01) were noted but were not persuasive. In particular the examiner noted that the evidence of detection in both diseased, non-diseased and alternative tissues fails to indicate any particular condition, diagnosis, treatment or cell tissue type and thus it is unclear to the examiner how the instant sequences can be considered diagnostic. In addition, there is no evidence of over expression in any particular diseased state, condition, or evidence that such polynucleotides can be used as a prognostic indicator in particular as no levels of such over expression appear to be indicated. Thus for the aforementioned reasons and a lack of evidence of such asserted utilities the rejection is maintained as previously set forth.

In the amendment of 4-17-02 applicant's submit a declaration under 37 CFR 1.132 describing experimental procedures performed in PS128 prostate cancer (CaP) tissue and benign prostatic hyperplasia (BPH) tissue and assert that the description is of a quantitative analysis demonstrating higher levels of expression in CaP definitively showing that PS128 is useful as a marker to identify CaP.

Applicants declaration and arguments filed 4-17-02 under 37 CFR 1.132 have been fully considered but are not persuasive. The declaration describes RT-PCR

analysis performed using the procedures as denoted in point 3 of the declaration. RNA was isolated, amplified via RT-PCR and quantities of PS128 bands obtained on electrophoresis were measured by pixel intensity as described. The results indicated that the amplified product exhibited higher pixel intensity in CaP vs BPH samples. However, the declaration does not speak to the relevance of the amplification procedure to any of the disclosed PS128 sequences in particular or to the elected sequence of SEQ ID NO:5, residues 1-276. Thus, it is not clear that expression of this region of the PS128 gene was measured via RT-PCR. Further, the skilled artisan readily recognizes the difference between quantitative and non-quantitative RT-PCR. For example, as Freeman et al., Biotechniqes, (1999 Jan) 26(1):112-125 teaches, successful quantitation involves correction for experimental variations in individual RT and PCR efficiencies, see in particular Abstract. As noted in Figure 1, quantitative RT-PCR requires an RNA standard to assess such variances. While applicants disclose that their methodology uses RT-PCR the declaration does not evidence any procedural methods, controls or standards which would indicate that the reactions were in fact quantitative. Thus, the declaration provides insufficient evidence for the conclusion that the subject matter of instant claims, in particular SEQ ID NO:5 residues 1-276 were overexpressed in CaP or would be useful in discerning CaP tissue from BPH tissue. Therefore the rejection is maintained absent particular evidence of the relevancy of the amplified material in the assay to the noted sequences claimed, in particular SEQ ID NO:5, residues 1-276 and evidence that the procedures used were in fact quantitative as asserted in applicants arguments and not non-quantitative as indicated by the

procedural evidence as set forth in the declaration.

Applicant's argue in the response of 5-19-03 that the previous declaration of Philip Hemken describes the quantitative analysis of levels of PS128 in prostate cancer and benign prostatic hyperplasia. The results are noted to indicate that PS128 expression is higher in CaP than BPH and thus that PS128 is useful as a marker to identify CaP

Applicant's arguments filed 5-19-03 have been fully considered but are not persuasive. As previously set forth above, "Applicants declaration and arguments filed 4-17-02 under 37 CFR 1.132 have been fully considered but are not persuasive. The declaration describes RT-PCR analysis performed using the procedures as denoted in point 3 of the declaration. RNA was isolated, amplified via RT-PCR and quantities of PS128 bands obtained on electrophoresis were measured by pixel intensity as described. The results indicated that the amplified product exhibited higher pixel intensity in CaP vs BPH samples. However, the declaration does not speak to the relevance of the amplification procedure to any of the disclosed PS128 sequences in particular or to the elected sequence of SEQ ID NO:5, residues 1-276. Thus, it is not clear that expression of this region of the PS128 gene was measured via RT-PCR. Further, the skilled artisan readily recognizes the difference between quantitative and non-quantitative RT-PCR. For example, as Freeman et al., Biotechniqes, (1999 Jan) 26(1):112-125 teaches, successful quantitation involves correction for experimental variations in individual RT and PCR efficiencies, see in particular Abstract. As noted in Figure 1, quantitative RT-PCR requires an RNA standard to assess such variances.

While applicants disclose that their methodology uses RT-PCR the declaration does not evidence any procedural methods, controls or standards which would indicate that the reactions were in fact quantitative. Thus, the declaration provides insufficient evidence for the conclusion that the subject matter of instant claims, in particular SEQ ID NO:5 residues 1-276 were overexpressed in CaP or would be useful in discerning CaP tissue from BPH tissue. Therefore the rejection is maintained absent particular evidence of the relevancy of the amplified material in the assay to the noted sequences claimed, in particular SEQ ID NO:5, residues 1-276 and evidence that the procedures used were in fact quantitative as asserted in applicants' arguments and not non-quantitative as indicated by the procedural evidence as set forth in the declaration." Such matters have not been addressed in the instant rebuttal and thus the rejection is maintained for the same reasons of record.

10. Claims 57-59, 62-63 and 66 also are rejected under 35 U.S.C. 112, first paragraph as set forth above. Specifically, since the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

11. Claims 57-59, 62-63 and 66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants claims recite the nucleic acid sequence of residues 1-276 of SEQ ID NO:5. Applicants point to support for the recitation at p. 4, lines 1-4, p. 6, lines 1-3, p. 11, lines 32-35 and p. 12, lines 1-2. However, the specification at such citations does not support the sequence of SEQ ID NO:5, residues 1-276 as claimed. Thus, such recitations constitute new matter absent evidence for support in the specification as originally filed.

Applicants argue in the response of 5-19-03 that the sequences of SEQ ID NO:5 residues 1-276 are the same as SEQ ID NO:4 residues 1-276 of the priority document and thus that adequate support is provided.

Applicant's arguments filed 5-19-03 have been fully considered but are not persuasive. While the sequences are the same as indicated by Applicant, these arguments do not address the recitation of "residues 1-276" as recited. Neither the priority document nor instant case appears to support the newly preferred residues in comparison to the full sequence previously recited. Thus, the recitation constitutes new matter absent clarification of support for the recitation of SEQ ID NO:5, residues 1-276. It is noted that the length of SEQ ID NO:4 and 5 in instant application is 346 residues in length while SEQ ID NO:4 of the priority document was 302 residues in length. Neither recitation is in accordance with instantly recited residues 1-276 and the 3' end of the molecules differ at particular residues.

Status of Claims

12. No claims are allowed.

Conclusion

13. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

14. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
July 28, 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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